REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 50-52 are being added. Support for these claims is found in the specification as filed.

Claims 34, 35, 37, 46-48 are currently being amended. The amendments 1) clarify the language regarding particular configurations of the device, 2) remove the qualifier "about" from the claimed frequency ranges; and 3) correct two inconsistencies in the claims in view of the application. First, the term laser "energy" has been replaced with the term "radiation" to make the usage consistent across the claims. Applicant believes that the term laser energy is essentially equivalent to laser radiation, but the latter is a more industry-accepted term. Second, the term "bacteria" has been replaced with "microbe". Applicant states in the title and throughout the specification that the apparatus is a *microbial elimination device*. The specification (e.g. at Example III) teaches the invention can be used on prokaryotic cells (bacteria) as well as eukaryotic cells (fungi), and that eukaryotic cells are actually more sensitive to the treatment. Further, the specification (paragraph 0073) notes that "it is concluded that 870 nm and 930 nm infrared energy is toxic to certain microbes." Thus, photodamage of microbes is the objective, and use of the term "bacteria" is seen as improperly limiting the invention, which photodamages microbes (both prokaryotes and eukaryotes), not simply bacteria. Other amendments are presented, which are discussed in the context of particular rejections, below.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

I. Rejections under 35 U.S.C. § 102

Claims 2, 8, 34 and 37 are rejected under 35 U.S.C. 102 (e) as being anticipated by Goodman. The Office asserts that the wavelength of Goodman is "about 870 nm"; the pulsing of the laser constitutes a control as claimed; and the device attaching the sensor to the finger is considered a digit clip. Applicant respectfully traverses this rejection in view of the claims as amended and for the following reasons.

Applicant notes the Office has considered the average of Applicant's range, and qualified it with the phrase "about" in asserting anticipation by Goodman. This is a mischaracterization of the prior claim, which recited "a first wavelength range of about 865 nm to about 875 nm"... The Office is not permitted to rewrite Applicant's claimed range in developing its rejections. Applicant notes that the antimicrobial effect is distributed primarily across a range of about 865 nm to about 875 nm (see paragraphs 0050-0051), and some antimicrobial effects are still observed at, for example and without limitation 863 or 877 nm. This is why Applicant claimed the range using the qualifier "about". However, solely for the purpose of advancing prosecution of this application, Applicant has amended the claim to remove the qualifier "about", and reserves the right to pursue this subject matter in related applications.

Goodman is cited as anticipating the first wavelength of "about 870 nm". However, no specific citation to this wavelength is provided by the Office, nor upon review is that specific wavelength actually disclosed by Goodman. The closest frequency disclosed is seen at Paragraph [0247] describing that "at 880 nm... there is a much smaller difference in the between the absorption coefficients between the two wavelengths", referring to 658 nm used for determining the oxygenation state of hemoglobin. Likewise Paragraph [0248] describes the isobestic point for hemoglobin at "approximately 880 nm". The Office seems to be more lenient with interpreting qualifiers in the prior art. However, the Office is reminded that "It is inappropriate to attempt to reconstruct the prior art or otherwise modify it in an attempt to anticipate structure which is not shown in the prior art". Harris-Hub Co. v. Lear Siegler, Inc. 179 U.S.P.Q. 469 (Ill. 1973).

Nevertheless, Goodman cannot anticipate the claimed invention. *Prior art which teaches a value or range that is very close to, but does not overlap or touch the claimed range does not anticipate the claimed range.* See, MPEP §2131.03. "[A]nticipation under §102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on §103 which takes differences into account." Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Claims 2, 8, 34, 37, 45, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Tromberg et al. The Office asserts that the wavelength of Tromberg et al is "about 870 nm" and "about 930 nm"; the pulsing of the laser constitutes a control as claimed; and the device attaching the sensor to the finger is considered a digit clip. Applicant respectfully traverses this rejection in view of the claims as amended and for the following reasons.

Tromberg et al provides an apparatus for performing frequency domain photon migration measurements on turbid media (breast tissue). Frequencies described are general ranges from 600 nm to 1200 nm; and specific frequencies of 672, 800, 806, 852, 896, 913 and 978 nm (see paragraph 0021). None of the specific frequencies recited are in Applicant's claimed ranges, but the broader disclosure encompasses the claimed ranges. However, this is not sufficient to anticipate the claims. *Prior art which teaches a range overlapping or touching the claimed range anticipates if the prior art range discloses the claimed range with "sufficient specificity".* See, MPEP §2131.03.

When the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with

"sufficient specificity" to constitute an anticipation of the claims. See, e.g., Atofina v. Great Lakes Chem. Corp, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. "[T]he disclosure of a range is no more a disclosure of the end points of the range than it is each of the intermediate points." Id. at 1000, 78 USPQ2d at 1424. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching. See MPEP §2131.02.

The Tromberg et al reference does not disclose Applicant's claimed range with sufficient specificity to constitute an anticipation under the statute. The Tromberg et al reference teaches a broad range and by comparison Applicant's claims are directed to a narrow range. In addition, the specific frequencies recited in paragraph 0021 do not fall within Applicant's claimed ranges. Moreover, the Tromberg et al reference lacks any disclosure about antimicrobial effects, so in addition to lacking any specificity as to Applicant's claimed ranges, the reference doesn't appreciate the antimicrobial properties of these ranges. Clearly, the Tromberg et al reference can't anticipate the instant claims, as it doesn't teach Applicant's system that outputs precise frequencies and powers to effectuate antimicrobial effects.

Claims 2, 8, 34, 37, 45, and 46 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Merilainen. The Office asserts that the wavelength of Merilainen is "about 870 nm" and "about 930 nm"; the pulsing of the laser constitutes a control as claimed; and the device attaching the sensor to the finger is considered a digit clip. Applicant respectfully traverses this rejection in view of the claims as amended and for the following reasons.

The Merilainen reference provides a similar case as Tromberg et al. The Merilainen paper describes general ranges of frequencies from 600 nm to 1000 nm; and specific frequencies of 775, 810, 850 and 913 nm (see Column 6, lines 25-30). None of the specific frequencies

recited are in Applicant's claimed ranges, but the broader disclosure encompasses the claimed ranges. However, this is not sufficient to anticipate the claims for the reasons discussed above.

In general, none of the cited references teach every limitation of the claims as amended. Claim 34 and the claims dependent therefrom require that the power of the delivered infrared radiation in the first and second wavelength ranges is the majority of the total power of near infrared radiation delivered to the infected site. Support for this amendment can be found throughout Applicants specification, e.g. at paragraphs 0050-0051 which state:

> In accordance with the present invention, it is critical that the laser wavelengths selected as approximating 870 nm and 930 nm, respectively, lie **predominantly** within the wavelength ranges of (1) 865 nm to 875 nm and (2) 925 nm to 935 nm. Instead of avoiding the 870 nm and 930 nm wavelengths as suggested in the prior art by optical tweezer procedures, the laser system and process of the present invention selectively combines them. With less heat deposition in the site being irradiated, a much enlarged therapeutic window of opportunity is available to the laser operator. In essence, the combined wavelengths of the present invention use less energy than do prior art procedures to effect bacterial destruction, i.e. the optical energy used in the present invention is less than the thermal energy used in the prior art. (emphasis added.)

As discussed above, Goodman does not overlap or touch the claimed ranges; Tromberg et al and Merilainen teach very broad ranges that overlap the claimed range but do not disclose the claimed range with sufficient specificity to meet the criteria for anticipation. Tromberg et al and Merilainen also teach specific near-IR frequencies that do not overlap or touch the claimed ranges. Importantly, none of the cited references teach the power of delivered by the first and second wavelengths is the majority of the total power of near infrared radiation output by the device.

For the above reasons, Goodman, Tromberg et al and Merilainen cannot anticipate the instant claims. Accordingly, Applicant requests withdrawal of the 35 U.S.C. 102(e) rejections, and allowance of the claims.

II. Rejections under 35 U.S.C. § 103

Claims 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in combination with Grable. Claims 35, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Tromberg et al or Merilainen in combination with Grable. Applicant respectfully traverses these rejections in view of the claims as amended and for the reasons discussed herein.

Claim 35 is deemed obvious over Goodman in view of Grable, in that Goodman is cited as teaching the device as claimed, but not a particular power. Grable is cited as providing powers in Applicant's range that are appropriate for diagnosing tissue.

Claims 35, 47 and 48 are deemed obvious over Tromberg et al or Merilainen in view of Grable, in that Tromberg et al and Merilainen are cited as teaching the device as claimed, but not a particular power. Grable is cited as providing powers in Applicant's range that are appropriate for diagnosing tissue.

As discussed above, none of the cited references Goodman, Tromberg et al and Merilainen actually teach Applicant's claimed device. As discussed above, Goodman does not overlap or touch the claimed frequency ranges of Applicant; Tromberg et al and Merilainen teach very broad ranges that overlap the claimed range but do not disclose the claimed range with sufficient specificity to meet the criteria for anticipation. Tromberg et al and Merilainen also teach specific near-IR frequencies that do not overlap or touch the claimed ranges. Importantly, none of the cited references teach the power of delivered by the first and second wavelengths is the majority of the total power of near infrared radiation output by the device.

Grable, common to the rejections, is universally cited as supplying critical disclosure regarding power outputs. *But the addition of Grable does not cure the deficiencies of Goodman, Tromberg et al and Merilainen.*

Applicant has provided a Declaration under 37 C.F.R. 1.132 that attests to the criticality of the claimed range of wavelength ranges that are microbicidal. See, MPEP 2144.05. "The law

is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See also MPEP § 716.02 - § 716.02(g) regarding criticality and unexpected results.

As Dr. Bornstein states in his Declaration, in all of the above cited references (Grable, Goodman, Tromberg et al, and Merilainen), near infrared wavelengths are employed in the devices because of their tissue penetration properties; but none of the cited references recognize the specific wavelengths 865-875 nm and 925-935 nm, or that these ranges are critical because these are the frequencies that provide for the cytotoxic effects of the claimed device. Thus, the cited references can't be deemed to apprehend or render obvious the claimed invention, which relies on power output *in these critical frequency ranges*.

Applicant has provided a Declaration under 37 C.F.R. 1.132 that attests as to the noncombinability of the Goodman, Tromberg et al, and Merilainen devices, with the power outputs disclosed by Grable. Applicant's power outputs are not the same as those disclosed by Grable, when you adjust for the pulse lengths. Note that Paragraph 0056 of Grable specification teaches generation of short (~100 femtosecond) laser pulses with peak pulse power of 67 kW. Thus, although the average power output of the Grable laser is only 0.75W, the generated radiation, if applied directly to human tissue, would cause damaging ablative effects owing to the very large peak power.

The Grable power levels are safe for use in the described laser-based diagnostic device only because Grable uses optics to spread the fast-pulsed beam out over multiple angles to form a fan shaped beam. (See, e.g., Grable paragraphs 0054, 0057 and Fig. 11). Note that in an alternate embodiment described at paragraphs 0143-0146, Grable applies the laser by sweeping the laser beam itself across the breast (instead of using a lens/mirror system to diverge the laser beam into a fan). In this configuration, Grable (paragraph 0146) explicitly notes that one must decrease the

power applied to the diagnostic site to levels lower than those listed for the primary embodiment. However, Grable provides no teaching that these reduced power levels are in Applicant's claimed range.

Thus as Dr. Bornstein states, the power output described in Grable is a tremendous amount of energy when not dispersed over a large area. Grable seems to agree, and specifically discloses that their resultant laser beam needs to be optically dispersed or swept in order to disperse the beam energy. By comparison, Applicant's invention provides for an approximate 8 Log reduction in unit energy per/pulse in the claimed invention as compared to Grable.

As Dr. Bornstein states, the high peak pulsed power outputs of Grable, when applied to the devices of Goodman, Tromberg et al, and Merilainen, would cause substantial tissue damage to any subject exposed to the laser beam. Furthermore, as Dr. Bornstein states, a person of skill in the art would recognize that the diagnostic devices described by Grable, Goodman, Tromberg et al, and Merilainen are designed for long beam exposure times, in that the devices are meant to be employed as monitoring or scanning devices, and as such a skilled artisan would recognize the undesirability of using high levels of energy/pulse, in devices where the subject will have a long exposure time to the laser beam. Merilainen describes constant irradiation of brain tissue to measure anaesthetic responses. Clearly, the power outputs of Grable are unsuitable in the Merilainen device. Dr. Bornstein states that, for such exposure time using the power output of Grable, the patient's brain and skull would be perforated by the laser. Similarly, Tromberg et al describe scanning systems for imaging tissues of a patient, and gives specific examples of using lasers tuned to near-IR frequencies, to analyze breast tissues for abnormalities. The power output of Grable in the Tromberg et al device would cause similar tissue damage/ablation to the imaged tissue.

Simply put, the cited references do not teach Applicant's invention, either alone or in combination, and as such can't render the claims obvious. Further rebutting the Office's assertion of obviousness, Applicant has provided in his Declaration, evidence that the invention addresses a long-felt need for a medical device to treat and manage infections. Applicant further

attests to the commercial success of the claimed device. Accordingly, Applicant requests withdrawal of the 35 U.S.C. 103(a) rejections, and allowance of the claims.

III. Rejections under Double Patenting

Claims 2, 8, 34, 34, 35, 37 and 45-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent Application No. 11/825550.

Claims 2, 8, 34, 34, 35, 37 and 45-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-122 of U.S. Patent Application No. 11/841348.

Claims 2, 8, 34, 34, 35, 37 and 45-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent Application No. 11/981486.

Claims 2, 8, 34, 34, 35, 37 and 45-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-64 of U.S. Patent Application No. 11/997665.

Claims 2, 8, 34, 34, 35, 37 and 45-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent Application No. 12/019336.

Applicant respectfully traverses the five provisional rejections for obviousness-type double patenting. In all five cases, the Office asserts that the cited applications which require elements A, B, C and D, encompass the instant application claims, which require elements A, B and C. Applicant disagrees with this characterization, in part because the Office has not identified the elements deemed as duplicative. The instant case might be construed as dominating the cited cases, but domination by itself, *i.e.,* in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection. See, MPEP

§804; In re Kaplan, 789 F.2d 1574, 1577-78, 229 USPQ 678, 681 (Fed. Cir. 1986); and In re Sarrett, 327 F.2d 1005, 1014-15, 140 USPQ 474, 482 (CCPA 1964).

Irrespective, the claims as amended render this assertion moot as the amendments provide further patentable distinctions between the claims of the instant application and the cited ones. Applicant notes the provisional nature of this rejection, and requests withdrawal of this rejection in view of the claims as amended, and in further consideration that neither the instant claims nor the cited ones are currently allowed or issued.

IV. Office Action's Response to Applicant's Arguments

The Office action states that it does not find Applicant's arguments with respect to previously made prior art rejections based on Parker and Rao. Applicant respectfully submits that the arguments presented in the Applicants previous response are sufficient to overcome the rejections based on Parker and Rao. Further, Applicants respectfully submit that the claims, as currently amended, further distinguish these references. For example, neither reference teaches or suggests delivering near IR radiation in both of applicants claimed wavelength ranges, where delivered power falls predominantly in these ranges.

V. Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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